

REMARKS/ARGUMENTS

The Examiner has objected to claim 45 on the basis of a lack of consistency with the specification for the terms “first electrode” and “ground electrode”. The claims have been amended to recite active and counter electrodes which is consistent with the specification, particularly page 55, paragraph 99. Applicants note however, that throughout the text of the specification the term “first electrode” has been used to indicate an active electrode and the term “second electrode” has been used to indicate an electrode in electrical contact with the power source to complete the circuit (hence a “ground” electrode or a “counter” electrode). Applicants submit that there was nothing inconsistent at all since the statutory provision of 35 U.S.C. 112 does not require slavish repetition and only requires a person of skill in the art to understand the scope of the claims.

The rejection of the claims as anticipated by McNichols et al. (U.S. Patent No. 5,697,896) is respectfully traversed. Applicants note that in the opening paragraph of the rejection, there is an inconsistency in the identification of the claims rejected based on McNichols. However, since in the summary sheet of the Office Action claims 45-65 and 71-72 stand rejected, Applicants presume that claims 45-48, 50-65 and 71-72 are the claims which are subject to this rejection.

Referring to a representative example of the claimed subject matter, e.g. claim 45 and Figure 18, it would be appreciated that the active and counter electrodes are located on opposite sides of the applicator. The electronics including the touch-sensitive switch in this embodiment are located between the active and counter electrodes. As explained in paragraph 99, a user's finger applied to the counter electrode 304 activates the switch and hence the circuitry to electrokinetically transport the medicament into the treatment site. Thus, by applying the

individual's finger to the counter electrode and applying pressure to activate the touch-sensitive switch, the circuit is activated and the applicator is held against the treatment site.

While the Examiner is correct in his identification of various elements found in the McNichols reference as set forth in the opening paragraph on page 3 of the Office Action , McNichols, contrary to the Examiners statement, is not capable of carrying out the steps recited in the method claims. That is, the McNichols reference does not respond to the steps recited in the claims.

Referring to Figure 4 of McNichols, both the donor electrode and the counter electrode are located side by side in the same plane adjacent one side of the McNichols device. Both the surfaces of the donor electrode and the counter electrode lie in intimate contact with the treatment site on the skin overlaid by the McNichols device. The donor and counter electrodes of McNichols are separated laterally by an insulator 420 to prevent electrical shorting. In McNichols, electrical current is driven from the donor electrode 412 through the donor reservoir 416, the skin surface, the subcutaneous tissue directly between the donor and counter electrodes and then back through the skin under the counter electrode to complete the circuit. The path of current flow is short, is only limited to the subcutaneous tissue area between the adjacent donor and counter electrodes and does not flow through the body as in the presently claimed invention.

As claimed, the counter and active electrodes lie on opposite sides of the applicator. The counter electrode is a tactile electrode located on a surface of the applicator for electrical contact with the individual's finger which also maintains the applicator against the treatment site. In this configuration, the user's body including through the individual's finger completes the electrical circuit between the active and counter electrodes. That is to say, an electrical circuit is completed through the applicator via the active electrode, the medicament, the individual's face

(assuming the treatment site is located on the face), the individual's torso, arm, hand and the counter or tactile electrode carried by the applicator. Not only are the active and counter electrodes far removed from each other in terms of body location, but the current flow between them is purposely diverted to follow a long arduous path. This ensures uniform distribution of current at the active electrode site.

In contrast, the McNichols device uses donor and counter electrodes in close proximity to one another. This results in an irregular distribution of the current under the donor electrode, i.e. the current distribution is far from uniform. It is well established that electrical charges and charge carriers always seek the shortest path between electrodes. Under the donor electrode in McNichols, the current density in the proximal area is necessarily higher than in the distal area relative to the location of the counter electrode. The electrical resistance of a shorter pathway is smaller than that of the longer pathway. A non-uniform current distribution will lead to a non-uniform delivery of medicament at the active electrode. Moreover, current concentration is potentially dangerous causing discomfort and possibly electrical burns. The present invention mitigates this harmful effect by altering the current flow path between the active and counter electrodes. As claimed the active and counter electrodes are separated, one from the other, by a great distance along the individual's body. The current flow is therefore diverted to follow a long path through the body. Under this condition, electrical charges and charge carriers, while still seeking the shortest path, follow more or less along the long pathways. This affords a uniform current flow under and throughout the active electrode site.

Fundamentally, claim 45 distinguishes from McNichols by locating the counter and active electrodes on opposite sides of the applicator together with a touch-sensitive switch

activated upon application of the individual's finger to the counter electrode such that the electrical circuit is completed through the individual's body as stated previously.

While claim 45 clearly distinguishes from McNichols, many of the dependent claims add features which likewise further distinguish from the McNichols reference. For example, claim 52 requires a tacky substance on the opposite side of the applicator to facilitate manipulation and application of the applicator to the treatment site. McNichols does not disclose this aspect of the claimed invention. Neither does McNichols disclose an electrically conductive material located on the opposite side of the applicator to enable electrical interconnection between the individual's finger and the counter electrode as set forth in claim 53. McNichols does not disclose stacked active and counter electrodes in processing circuitry as set forth in claim 55. Dependent claim 56 requires the tacky substance in the stacking of the electrodes in the processing circuitry. Claim 57 requires a touch-sensitive switch to be in stacked relation with the electrodes in the processing circuitry. Claim 59 likewise requires the stacked relation of the medicament and electrically conductive material with the electrodes in the processing circuitry.

Referring to claim 60, it requires the active and counter electrodes to lie along opposite sides of the applicator. The method includes applying the applicator to the treatment site by placing a finger for electrical contact with the counter electrode on the opposite side of the applicator remote from the side containing the active electrode to complete the electrical circuit through the individual's finger, the treatment site, the medicament and the active and counter electrodes. McNichols does not provide active and counter electrodes on opposite sides of the applicator nor does McNichols complete an electrical circuit by placing a finger on the counter electrode on the opposite side of the applicator remote from the active electrode. To the extent

McNichols requires the individual to actuate switch 18, the electrical circuit is nonetheless not completed through the individual's finger activating switch 18 in McNichols.

To summarize, McNichols has laterally juxtaposed donor and counter electrodes applicable to and directly adjacent the treatment site respectively and does not provide active and counter electrodes on opposite sides of the applicator. In the present invention, the actuation of the applicator by the individual's finger from the side of the applicator opposite the active electrode and the use of a tacky substance on the counter electrode enables the applicator to be freely manipulated and oriented relative to the treatment site. Also the current path is long, i.e. through the individual's body including the individual's finger, thereby mitigating problems associated with current concentration and non-uniform delivery of medicine at the treatment site under the active electrode. Due to the adjacency of the donor and counter electrodes in McNichols, i.e. essentially adjacent the treatment site, current density problems will arise.

The rejection of claim 49 based on a combination of McNichols and Lattin et al. (U.S. Patent No. 4,406,658) is respectfully traversed. The Examiner acknowledges McNichols does not disclose a vibrator. The Examiner identifies a vibrator 60D in the control circuit 60 of Lattin stating that it would have been obvious to include a vibrator as suggested by Lattin for purposes of indicating the device's activation. The "vibrator" referenced by the Examiner in Lattin at 60D is a monostable multivibrator (column 9, line 53). A monostable multivibrator is a circuit element that delivers one output pulse for each input pulse. Applicants attach a copy of a monostable multivibrator definition taken from a standard text titled "The Illustrated Dictionary of Electronics". The monostable multivibrator of Lattin has absolutely nothing to do with the physical vibration required by claim 49 to indicated activation of the applicator and it's working status.

HENLEY ET AL.
Appl. No. 10/724,160
July 14, 2005

Accordingly, reconsideration and allowance of the claims pending in this application is
respectfully requested.

Respectfully submitted,

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